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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/351,985	07/12/99	BRAUN	F A32585-PCT-U

021003
BAKER & BOTTS
30 ROCKEFELLER PLAZA
NEW YORK NY 10112

HM22/0503

EXAMINER

WANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

05/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/351,985

Applicant(s)

BRAUN ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

The receipt of the amendments and remarks submitted February 21, 2001 is acknowledged.

Claim Rejections 35 U.S.C. – 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The term "deep-frozen" in claims 1, 6 and 12 is a relative term which renders the claim indefinite. The term "deep-frozen" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claims are indefinite as to the freezing temperature employed for freezing the thrombocytes or thrombocyte fragment. Applicants' remarks regarding the definition of "deep frozen" have been fully considered, but not persuasive. Particularly, applicants merely state person skill in the art would understand the meaning of "freezing" and do address the issue of "deep frozen."

Claim Rejections 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1, 4, 6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Read et al. (U.S. Patent 5,902,608).

Read et al. teaches a surgical composition comprising thrombocytes (blood platelet) containing growth factor. The composition is sterile. Deep-freezing and/or lyophilization prepare the thrombocytes. See, particularly, the abstract, the claims and the example 1 on column 5. Since the composition is made from biological materials, it inherently contains biomaterials. Further, note the claims herein read on any lyophilized blood product containing platelet for medicinal purpose since it is well known in the art that platelet contains growth factor and such product is always sterilized. Therefore, claims 1, 4 and 6 are also clearly anticipated by the statement in column 1, lines 32-38, wherein Read shows that lyophilized platelet is an old and well-known product in the art for therapeutic purpose.

Claim Rejections 35 U.S.C. - 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1–20 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Read et al. (US 5,902,608) and Patat et al. (US 5,589,462 of record) in view of Delmas (US 5,618,663 of record), Dimoudis et al. and (CA abstract, AN 1996:313895, 1996, of record)

8. Read et al. teaches a surgical composition comprising thrombocytes (blood platelet) containing growth factor. The composition is sterile. Deep-freezing and/or lyophilization prepare

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the thrombocytes. See, particularly, the abstract, the claims and the example 1 on column 5.

Patat et al. teaches a medicinal product for topical application for the promotion of wound healing, which comprising frozen growth factor containing thrombocytes. See, particularly, the abstract, column 1, line 49 bridging column 2, line 7, column 2, line 21 bridging column 3, line 14 and column 6, lines 24-31. The freezing temperature is below -15°C . See, particularly, column 4, lines 31-36. The reference teaches that thrombocytes are known to be one of the principal sources of growth factors. See, column 1, lines 54-64. Growth factors along with other components such as fibronectin, thrombin and collagen are known to be useful for promoting wound healing. See, particularly, column 1, lines 5-41. The reference teaches that the platelet (thrombocyte) enriched plasma contains about 10^8 to 5×10^8 thrombocytes. See, column 4, lines 13-29. The reference further teaches that the medicinal product contains other components normally present in a platelet extract, e.g., protein, fibrinogen. See, column 3, lines 6-24.

The primary references do not expressly teach inactivation of viruses with the thrombocytes or the employment of additional epithelial cells and/or keratinocytes and/or embryonic and/or fetal cells and/or liposomes and lyophilization of thrombocytes.

However, Delmas teaches inactivation of viruses with a thrombocyte products for healing is necessary. See, particularly, column 6, lines 35-46. Dimoudis et al. teach that epithelial cell is known to be useful in wound healing composition. See the title and the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a sterile platelet factor enriched thrombocyte compositions with inactivation of viruses and by the addition of other known wound healing components such as epithelial cell.

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A person of ordinary skill in the art would have been motivated to make a sterile platelet factor enriched thrombocyte compositions with inactivation of viruses and by the addition of other known wound healing components such as epithelial cell because both using thrombocytes or the growth factor extract from the thrombocytes for wound healing is known. The inactivation of viruses is well known to be necessary for any topical wound healing composition to avoid any possible transmission of disease. The addition of epithelial cells is seen to be obvious since epithelial cells are known to be useful in wound healing composition. The combination of the above known ingredients is seen to be obvious because it is prima facie obvious to combine two or more components each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two known germicides sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069.

Regarding claim 10, the employment of a composition known to be useful for promoting wound healing for wound healing is seen to be obvious.

9. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

10. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., sustained release of growth factor) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Shengjun Wang

AU 1617

April 26, 2001



RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200